Order Code RS22177
Updated November 14, 2005

The Legal Regulation of Sales of Over-the-Counter Cold Medication

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Summary

In response to a growing problem with illegal methamphetamine production and abuse, a number of states have recently enacted laws that impose sales restrictions on over-the-counter cold medications that contain methamphetamine precursor chemicals such as ephedrine, pseudoephedrine, and phenylpropanolamine. On the federal level, the Drug Enforcement Agency (DEA) is the primary agency that regulates sales restrictions on such drug products under the Controlled Substances Act (CSA). The federal statute, however, currently imposes fewer sales restrictions than are imposed under some state laws, although the following bills, which would expand federal regulation of over-the-counter drugs that contain methamphetamine precursor chemicals, have been proposed in the 109th Congress: H.R. 314, H.R. 1056, H.R. 1083, H.R. 1350, H.R. 1378, H.R. 1446, H.R. 3324, H.R. 3513, H.R. 3568, H.R. 3889, H.R. 3955, S. 103, and S. 430.

In response to rising rates of methamphetamine production and abuse across the country, many elected officials and law enforcement officers have recently begun to explore new methods of curtailing such activities. One regulatory option gaining in popularity is to target the precursor chemicals that are key ingredients in methamphetamine production by placing restrictions on over-the-counter (OTC) sales of certain drug products — most notably, cold medicines — that contain ephedrine, pseudoephedrine, and phenylpropanolamine.[1] Because drug products that contain these three precursor chemicals can easily be converted into methamphetamine and because such medications are readily available at many retail outlets, limiting retail sales and reducing the opportunity for theft of these medications is expected to reduce methamphetamine production and abuse.

[1] In 2000, the FDA initiated action to remove phenylpropanolamine from the market due to safety concerns. Although many drug manufacturers voluntarily discontinued products containing phenylpropanolamine, some products continue to remain on the market. Therefore, the DEA continues to regulate the chemical. Clarification of the Exemption of Sales by Retail Distributors of Pseudoephedrine and Phenylpropanolamine Products, 69 FR 2062, 2062 (Jan. 14, 2004). *See also*, Food and Drug Administration, Phenylpropanolamine (PPA) Information Page, [http://tv.zap2it.com/tveditorial/tve_main/1,1002,271%7C95861%7C1%7C,00.html].

In general, legislative efforts to limit sales of OTC cold and allergy remedies that contain methamphetamine precursor chemicals include proposals to: require such products to be placed behind the counter; restrict sales to licensed pharmacies only via a prohibition on sales in other retail stores; limit the number of packages that can be purchased in a single transaction; and require customers to provide identification and a signature upon purchase. Proponents of such restrictions argue that such limits are the best way to prevent methamphetamine-related crime, but opponents contend that these

restrictions limit access for law-abiding citizens who simply wish to buy medicine at the local convenience store when they catch a cold.[2]

Current regulation of OTC medications that contain methamphetamine precursor chemicals consists of a patchwork of federal and state laws in an array of areas. At the federal level, the Drug Enforcement Agency (DEA) enforces the Controlled Substances Act (CSA), which is a federal statute that establishes criminal and civil sanctions for the unlawful possession, manufacturing, distribution, or importation of controlled substances.[3] The Food and Drug Administration (FDA) regulates OTC drugs under the Federal Food, Drug, and Cosmetic Act (FFDCA), which governs, among other things, the safety and efficacy of OTC medications, including the approval, manufacturing, and distribution of such drugs.[4] At the state level, state law enforcement agencies oversee the enforcement of state controlled substances laws, and state boards of pharmacy regulate pharmacy practice. Thus, some of the laws that govern OTC medications that contain methamphetamine precursor chemicals vary from state to state. Currently, the states appear to be taking a more active role than the federal government in pursuing legislation to restrict OTC sales of cold remedies that can be used to make methamphetamine. Both federal and state laws are detailed below.

Federal Law

As noted above, the CSA is a federal statute that establishes criminal and civil sanctions for the unlawful possession, manufacturing, distribution, or importation of controlled substances. The primary purpose of the CSA is to facilitate the legal distribution of controlled substances for legitimate medical purposes while preventing their diversion for illegal manufacture, distribution, and use. Over the years, however, the scope of the CSA has expanded from controlling illegal drugs to regulating the chemicals that are used in the illicit production of those drugs. Since many of these precursor chemicals have legitimate uses, their regulation is generally less stringent, and some, like ephedrine, pseudoephedrine, and phenylpropanolamine, are legally marketed as non-controlled ingredients in certain OTC drug products, even though they are otherwise listed chemicals that are regulated under the CSA.[5]

Currently, federal law places some restrictions on retail sales of products containing methamphetamine precursor chemicals. In general, under the CSA, sales of listed chemicals that are contained in drug products that are lawfully marketed or distributed under the FFDCA are not regulated transactions,[6] which means that retailers are not

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[2] Margot Roosevelt, *The Cold-Pill Crackdown*, TIME, Feb. 7, 2005, at 56.

[3] 21 U.S.C. § 801 et seq. For more information on the Controlled Substances Act, see CRS Report 97-141, *Drug Smuggling, Drug Dealing and Drug Abuse: Background and Overview of the Sanctions Under the Federal Controlled Substances Act and Related Statutes*.

[4] 21 U.S.C. §§ 301 et seq.

[5] Drug Enforcement Administration, U.S. Chemical Control, [http://www.usdoj.gov/dea/concern/chemical_control.html].

[6] 21 U.S.C. § 802(39)(A)(iv). Other activities are also excluded from the definition of regulated transactions, such as any transaction in a chemical mixture that the Attorney General has by (continued...)

subject to the statute's detailed registration, record keeping, and reporting requirements,[7] nor are they required to comply with the customer identification or drug security requirements.[8] This provision reflects the notion that the effort to regulate controlled substances should not unduly interfere with public access to OTC drug products that have legitimate medical uses.

Due to concerns about methamphetamine production and distribution, however, sales of FDA-approved drug products containing ephedrine, pseudoephedrine, and phenylpropanolamine *are* regulated transactions, with two notable exceptions. First, a sale is not a regulated transaction if the package size contains no more than 3 grams of pseudoephedrine or phenylpropanolamine and if the overall transaction is limited to no more than 9 grams of pseudoephedrine or phenylpropanolamine,[9] or, for combination ephedrine products, if the overall threshold is limited to 24 grams for a single transaction.[10] Second, the sale of ordinary OTC pseudoephedrine or phenylpropanolamine products by retail distributors — defined to include grocery stores, general merchandise stores, drug stores, or other entities whose sale of OTC products that contain methamphetamine precursor chemicals are limited almost exclusively to sales for personal use[11] — is not a regulated transaction.[12] Under this exception, the definition of "ordinary OTC pseudoephedrine or phenylpropanolamine product" is defined as a product containing pseudoephedrine or phenylpropanolamine that is:

> except for liquids, sold in package sizes of not more than 3.0 grams of pseudoephedrine base or 3.0 grams of phenylpropanolamine base, and that is packaged in blister packs, each blister containing not more than two dosage units, or where the use of blister packs is technically infeasible, that is packaged in unit dose packets or pouches; and for liquids, sold in package sizes of not more than 3.0 grams of pseudoephedrine base or 3.0 grams of phenylpropanolamine base.[13]

In addition, the CSA makes it unlawful for an individual to possess a listed chemical such as ephedrine, pseudoephedrine, or phenylpropanolamine with intent to engage in the unauthorized manufacture of a controlled substance or to possess or distribute a listed chemical while knowing or having reasonable cause to believe that the chemical will be used in the unauthorized manufacture of a controlled substance.[14]

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[6] (...continued)
regulation exempted because the mixture is formulated to prevent the illicit production of a controlled substance. *Id.* at § 802(39)(A)(v).

[7] *Id*. at §§ 823(h), 830.

[8] 21 C.F.R. §§ 1310.07, 1309.71.

[9] 21 U.S.C. § 802(39)(A)(iv)(II).

[10] 21 C.F.R. § 1300.02(28)(i)(D)(2).

[11] *Id*. at § 1300.02(29).

[12] 21 U.S.C. § 802(39)(A)(iv)(I)(aa).

[13] *Id*. at § 802(45).

[14] *Id*. at § 841(c).

As noted above, the FDA also has regulatory authority over OTC drugs that contain methamphetamine precursor chemicals. It is the FFDCA that governs, among other things, the safety and efficacy of OTC medications, including the approval, manufacturing, and distribution of such drugs.[15] Under the statute, there are two regulatory classifications for drugs: either prescription or OTC. In general, OTC drugs, unlike prescription drugs, do not pose a risk of misuse or abuse and can be safely and effectively used without the supervision of a medical practitioner. Thus, OTC drugs are usually publicly available for consumers to purchase for treatment of self-diagnosed conditions.

Because the FFDCA's regulatory scheme appears to contain only two classifications for drugs — either prescription or OTC — it is unclear whether the FDA has the legal authority to establish a third classification for drugs that could be sold behind the counter (BTC) with the advice and assistance of a licensed pharmacist. A category for BTC drugs would make such medications more available than prescription drugs but would preserve some degree of professional oversight for drugs that pose more risks than the average OTC medication. Indeed, some states have begun requiring pharmacies to move cold medications behind the counter in an effort to prevent their diversion for methamphetamine production. Because it is uncertain whether the FDA has the legal authority to establish a BTC classification for drugs, however, it is unclear whether the FDA could, short of reclassifying OTC drug products that contain methamphetamine precursor chemicals as prescription drugs, impose restrictions similar to the BTC requirements established in some states.[16]

On the other hand, the DEA does have authority to impose sales restrictions on regulated chemicals, including the authority to require that drug products that contain listed chemicals be kept behind the counter where only retail employees have access, and the agency has imposed this requirement with respect to single-entity ephedrine drug products, which are medications that contain ephedrine as the sole active medicinal ingredient.[17] The DEA also proposed similar restrictions for combination ephedrine products — drug products that contain ephedrine as well as therapeutically significant amounts of another active medicinal ingredient — but ultimately did not include such a requirement in its regulations.[18] However, the DEA requirement that single-entity ephedrine products be kept behind the counter applies to all retail outlets, not just pharmacies, and is designed to make it more difficult for the product to be stolen off store shelves. This type of BTC requirement allows retail establishments to continue to sell such medications and should be distinguished from proposals to establish a separate class of BTC drugs that would be kept behind the *pharmacy* counter and that would involve the

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[15] *Id*. at §§ 301 et seq.

[16] Robert I. Field, *Support Grows for a Third Class of "Behind-the-Counter" Drugs*, P&T Journal (May 2005), [http://www.ptcommunity.com/ptJournal/fulltext/30/5/PTJ3005260.pdf]; Rita Rubin, *Rx Out of the Box*, USA Today, Feb. 8, 2005, at 1D.

[17] 21 C.F.R. § 1309.71.

[18] Implementation of the Comprehensive Methamphetamine Control Act of 1996; Regulations of Pseudoephedrine, Phenylpropanolamine, and Combination Ephedrine Drug Products and Reports of Certain Transactions to Nonregulated Persons, 67 FR 14853, 14855-56 (March 28, 2002).

oversight of a pharmacist, thereby preventing retail establishments such as grocery stores and convenience stores from selling such drug products.

In recent years, several congressional legislators have introduced bills to expand federal regulation of OTC drugs that contain methamphetamine precursor chemicals. In the 109th Congress, the following bills were introduced: H.R. 314, H.R. 1056, H.R. 1083, H.R. 1350, H.R. 1378, H.R. 1446, H.R. 3324, H.R. 3513, H.R. 3568, H.R. 3889, H.R. 3955, S. 103, and S. 430. Many of these proposed bills would alter federal law by adopting legislative reforms that are similar to those recently enacted at the state level.

If Congress enacted new legislation, then the preemption provisions of the CSA would determine the effect of federal law on existing state laws.[19] Under the statute's existing preemption requirements,[20] federal controlled substances law preempts state law where state requirements are weaker but not where state requirements are stronger. Thus, if Congress enacted new legislation with regard to cold medications that contain methamphetamine precursor chemicals, states would remain free to enact stronger laws, as long as the federal law made no changes to the CSA's current preemption provisions.

State Laws

As noted above, state boards of pharmacy regulate the practice of pharmacy, and state law enforcement agencies oversee state controlled substances laws. While states are not permitted to enact laws in these areas that are less strict than federal law, states may pass laws that are stricter, and several states have done so recently with respect to cold medications that contain methamphetamine precursor chemicals. Most of these new laws have established additional sales restrictions on such medications, including requiring these drugs to be placed behind the counter, limiting the amount that can be purchased, requiring customers to provide identification and a signature upon purchase, and placing such drug products on the schedule of controlled substances, thus effectively eliminating sales by non-pharmacy retail stores.

The first state to establish such restrictions was Oklahoma, which, in 2004, enacted a new law designed to crack down on the illegal production and abuse of methamphetamine in the state. Under the new law, Oklahoma added drug products containing pseudoephedrine — except for combination products in liquid or gel form —

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[19] The preemption doctrine derives from the Supremacy Clause of the Constitution, which establishes that the laws of the United States "shall be the supreme law of the land; and the judges in every state shall be bound thereby, any thing in the Constitution or laws of any State to the contrary notwithstanding." U.S. CONST. art. VI, cl. 2. In applying this constitutional mandate, courts have recognized both express and implied forms of preemption, which are "compelled whether Congress' command is explicitly stated in the statute's language, or implicitly contained in its structure and purpose." Gade v. National Solid Wastes Management Association, 505 U.S. 88, 97 (1992) (quoting Jones v. Rath Packing Co., 430 U.S. 519, 525 (1977)).

[20] 21 U.S.C. § 903. ("No provision of [the CSA] shall be construed as indicating an intent on the part of the Congress to occupy the field in which that provision operates, including criminal penalties, to the exclusion of any State law on the same subject matter which would otherwise be within the authority of the State, unless there is a positive conflict between that provision ... and that State law so that the two cannot consistently stand together.")

to its list of Schedule V controlled substances and imposed an array of new sales restrictions, including the following: (1) such drug products may only be sold behind the pharmacy counter by, or under the supervision of, a licensed pharmacist or registered pharmacy technician; (2) individuals who purchase such drug products must provide photo identification and must sign a written log of the transaction; and (3) in the absence of a prescription, individuals may not purchase more than 9 grams of such products within any thirty-day period.[21]

According to news reports, multiple states have followed Oklahoma's lead. At least twelve other states have enacted laws that place sales restrictions on cold medications, including Arkansas, Georgia, Illinois, Iowa, Kansas, Kentucky, Mississippi, Oregon, South Dakota, Tennessee, West Virginia, and Wyoming, and legislation has been proposed in at least 20 other states.[22]

More recently, Oregon further strengthened its laws with regard to cold medications that contain methamphetamine precursor chemicals. Enacted in 2005, the new legislation adds ephedrine, pseudoephedrine, and phenylpropanolamine to the controlled substances schedule,[23] making Oregon the first state in the nation to require prescriptions for medications that contain these chemicals.

In addition, out of concern about theft of cold remedies and in search of a uniform sales policy in the face of differing state requirements, several national chain stores that sell drugs containing methamphetamine precursor chemicals have voluntarily adopted new practices with respect to these products. For example, Wal-Mart intends to require customers to show identification and provide a signature before purchasing such medicines, and Walgreens and Kmart limit the number of packages that can be purchased in a singe transaction. Likewise, Target plans to remove certain products from shelves in stores without a pharmacy and to move the drugs behind the counter in stores with pharmacies.[24] Meanwhile, drug manufacturers, who are fearful of reduced profits in the wake of new sales restrictions, are reportedly investigating how to develop alternative drug products that cannot be as readily converted into methamphetamine.[25]

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[21] 63 Okl. St. § 2-212.

[22] Larry Copeland, *States Limiting Sales of Cold Remedies*, USA Today, April 26, 2005, at 1A; Lois Romano, *Cold-Medicine Curbs Cited in Drug Effort; Number of Okla. Meth Labs Drops Sharply*, Wash. Post, Feb. 19, 2005, at A03.

[23] 2005 Ore. ALS 706.

[24] Margaret Webb Pressler, *Retailers Restrict Some Cold Medicines; Ingredient Can be Used to Make Meth*, Wash. Post., May 14, 2005, at A01. Copeland, *supra* note 19.

[25] Roosevelt, *supra* note 2 at 57.